

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE TRICOR INDIRECT PURCHASER
ANTITRUST LITIGATION

C.A. No. 05-360 (KAJ)
(consolidated)

THIS DOCUMENT RELATES TO:
PAINTERS' DISTRICT COUNCIL NO.30
HEALTH AND WELFARE FUND and
RICHARD G. WILDE, C.A. No. 05-360 (KAJ)

VISTA HEALTH PLAN, INC. and ROSS LOVE,
C.A. No. 05-365 (KAJ)

PENNSYLVANIA EMPLOYEES BENEFIT
TRUST FUND, C.A. No. 05-390 (KAJ)

JURY TRIAL DEMANDED

ALLIED SERVICES DIVISION WELFARE
FUND and HECTOR VALDES,
C.A. No. 05-394 (KAJ)

DIANA KIM, C.A. No. 05-426 (KAJ)

ELAINE M. PULLMAN, NEIL PERLMUTTER,
HELENA PURLMUTTER and LULA RAMSEY,
C.A. No. 05-450 (KAJ)

PHILADELPHIA FEDERATION OF TEACHERS
HEALTH AND WELFARE FUND,
C.A. No. 05-467 (KAJ)

CINDY CRONIN, C.A. No. 05 482 (KAJ)

CHARLES SHAIN and SANDRA KRONE,
C.A. No. 05-475 (KAJ)

LOCAL 28 SHEET METAL WORKERS,
C.A. No. 05-516 (KAJ)

ALBERTO LITTER, C.A. No. 05-695 (KAJ)

END PAYOR PLAINTIFFS' CONSOLIDATED CLASS ACTION COMPLAINT

[REDACTED PUBLIC VERSION]

Plaintiffs in the above-referenced action (collectively "End Payor Plaintiffs"), individually and on behalf of all others similarly situated, for their consolidated complaint against defendants Abbott Laboratories ("Abbott"), Fournier Industrie et Sante, and Laboratoires Fournier, S.A. (collectively "Fournier" and collectively with Abbott "Defendants"), upon knowledge as to themselves and their own acts, and upon information and belief as to all other matters, allege as follows:

NATURE OF THE ACTION

1. This class action is brought under the federal antitrust laws and the antitrust and/or deceptive practice statutes of twenty-three states and the District of Columbia to remedy anti-competitive actions by Defendants to foreclose generic competition for cholesterol-lowering drugs that contain the active pharmaceutical ingredient ("API") fenofibrate. Abbott and Fournier market, and have marketed, fenofibrate products under the brand-name TriCor®. Abbott's U.S. sales of TriCor® totaled \$779 million in 2004.

2. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. §355 (the "Hatch-Waxman Act") to expedite the introduction of generic drugs and bring down the cost of prescription drugs. Unfortunately, the Hatch-Waxman Act's unique provisions have been repeatedly abused by pharmaceutical manufacturers to the exact opposite effect. Branded pharmaceutical manufacturers have developed tactics that exploit the provisions of the Hatch-Waxman Act and the complex market for prescription drugs to wrongfully stall the marketing of generic drugs and perpetuate brand exclusivity long beyond the expiration of patents on chemical compounds.

3. The Federal Food and Drug Administration ("FDA") generally does not consider

whether a proposed new drug is better than existing formulations of drugs using the same active ingredient and intended for the same therapeutic purposes. Instead, the FDA considers whether a proposed new drug is better than the placebo — *i.e.*, nothing. If a new formulation of an existing drug is just as effective as an old formulation, the FDA will approve the drug *so long as it is more effective than nothing*. A new formulation may have some minor modification — *e.g.*, the active ingredient may be delivered to the body in a slightly different way — that is different for the sake of being different, and for which a patent is sought. If a patent of some sort is issued, it is immediately listed with the FDA and, under the Hatch-Waxman Act, any company that seeks to market a generic version of the drug must respond to the patent, by either agreeing to not seek market entry until the expiration of the patent or, in the case of a “Paragraph IV Certification,” challenging the patent validity or denying infringement. Upon notice of a Paragraph IV Certification, the brand manufacturer has the opportunity to foreclose or delay FDA approval for up to 30 months by merely initiating a patent infringement lawsuit, *whether or not it is meritorious*.

4. In this case, Abbott and Fournier have implemented and are pursuing a scheme to unlawfully maintain and prolong their monopoly position in the market for fenofibrate products.

[REDACTED]

This scheme abuses aspects of the complex health care delivery system and regulatory environment to deprive doctors and consumers of an opportunity to choose generic versions of fenofibrate formulations. The scheme keeps a step ahead of would-be generic competitors by delaying generic competition for its initial fenofibrate formulations, shifting the market to “new and improved” formulations that are altered only to avoid

bioequivalence with the earlier formulations, and then withdrawing their initial formulations from healthcare databases. The act of withdrawing their initial formulations from healthcare databases is unnecessary to market their "new and improved" formulations, and has the purpose and effect of erecting substantial barriers to entry on would-be generic competitors by ensuring that once a generic company is able to launch a competitive fenofibrate product, it will have to do so without the benefits of generic classification that would have been available but for the scheme. Because the old formulation branded product no longer exists, the new competitive product: (i) cannot be marketed as a generic; and (ii) cannot be substituted for Abbott's and Fournier's next generation TriCor® products.

5. Plaintiffs do not challenge Abbott's and Fournier's right or ability to apply to the FDA for approval of new fenofibrate formulations. Instead, Plaintiffs' challenge Abbott's and Fournier's affirmative, anticompetitive conduct to destroy the market for existing fenofibrate formulations, and thereby preclude generic competition. The components of Abbott's and Fournier's scheme, as alleged more fully below, includes the following:

- (a) Abbott and Fournier bring a particular formulation of a TriCor® product to market;
- (b) When Abbott and Fournier learn that generic competitors have developed and seek to sell lower-cost bioequivalent generic versions of the TriCor® product, Abbott and Fournier engage in a range of practices which have the purpose and effect of delaying the launch of competitive generic products until after they are able to launch a new formulation of their TriCor® product;
- (c) During the period when Abbott's and Fournier's delay tactics block

competitive generic drug rivals from the market, Abbott and Fournier exploit their monopoly in fenofibrate products to charge supracompetitive prices for TriCor® products. Those prices are far higher than the prices generic competitors would charge if they were able to sell their bioequivalent versions of TriCor® products;

(d) Once market entry by competitive generic drug products appears imminent, Abbott and Fournier begin selling a *new* formulation of a TriCor® product. The new formulation is the same medicine, used for the same indications, as the existing formulation. Abbott and Fournier take affirmative steps to convert customers from the existing formulation to the new formulation before the competitive generic products are available for sale;

(e) Despite Abbott's and Fournier's efforts to convert them, not all patients or doctors would switch from the prior formulation to the new formulation. Accordingly, Abbott and Fournier have taken affirmative steps to deprive them of a choice and, at the same time, eliminate a generic market for the prior formulation before the competitive generic versions are available to the public. In 2002, Abbott and Fournier removed its brand reference for TriCor® capsules from the National Drug Data File® ("NDDF"), so that the branded drug code reference no longer exists for purposes of generic substitution laws or for purposes of health care providers' pharmaceutical benefit programs. Defendants recently repeated this maneuver with its market shift to new tablet formulations.

6. As a result of this scheme, once a generic manufacturer is able to start selling a product that is bioequivalent to a prior TriCor® formulation — and therefore could be substituted by a pharmacist for the prior branded product — the market for that product has been switched to the new product. Because the would-be generic formulation is bioequivalent to the

prior brand formulation, pharmacists and others cannot legally substitute the product for the new TriCor® product, even though the products are indicated for the same uses. The product switch and the withdrawal of the NDDF code effectively eliminates generic competition that otherwise would have arisen.

7. Abbott's and Fournier's scheme unreasonably restrains competition even if their patent infringement actions are deemed lawful petitioning activity. If Abbott and Fournier simply launched their new products, without affirmatively destroying the market for the prior product, consumers would benefit from the existence of competition in sales of fenofibrate products. Instead, because Abbott and Fournier have improperly staved off generic competition and could potentially continue to do so indefinitely, Plaintiffs and members of the Class have been forced to pay supracompetitive prices for and are deprived of choices among fenofibrate products.

8. In addition, Abbott and Fournier had no factual basis to allege patent infringement when it brought suit against generic manufacturer Teva concerning its application to market 54 mg and 160 mg generic fenofibrate tablets, rendering the actions "shams." Teva had provided samples of its generic fenofibrate tablets to Abbott and Fournier before Abbott and Fournier filed suit, but Abbott and Fournier performed no tests of any kind on the tablets, including tests to analyze whether or not Teva's tablets might infringe Abbott's and Fournier's patents. Moreover, Abbott's and Fournier's procurement and efforts to enforce four patents — U.S. Patent No. 6,074,670 (the "670 Patent") U.S. Patent No. 6,277,405 (the "405 Patent"), U.S. Patent No. 6,589,552 (the "552 Patent") U.S. Patent No. 6,0652,881 (the "881 Patent") (collectively referred to as the "Stamm Patents") — do not constitute lawful petitioning activity because

Fournier committed inequitable conduct before the PTO in the prosecution of all four of the Stamm Patents.

9. This class action is brought on behalf of all end-payors (*i.e.*, consumers and other persons or entities that pay for prescription for family members, employees or insureds) who purchased or paid for fenofibrate products, including TriCor® products since April 9, 2002. In Count I, Plaintiffs seek a judgment pursuant to § 16 of the Clayton Act, 15 U.S.C. § 26, enjoining the continuation of Defendants' unlawful monopolistic practices in violation of §2 of the Sherman Act, 15 U.S.C. §2. Neither Plaintiffs nor the Class seek any relief under §4 of the Clayton Act, 15 U.S.C. § 15.

10. In Count II, Plaintiffs and the Class also seek damages for Defendants' violations of the antitrust and/or deceptive practice statutes of Arizona, California, District of Columbia, Florida, Iowa, Kansas, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Vermont, West Virginia and Wisconsin (collectively, the "Indirect Purchaser States").

11. In Count III, Plaintiffs and the Class seek equitable remedies as to Defendants' unjust enrichment.

12. In Count IV, Plaintiffs and the Class seek damages for deceptive trade practices in violation of Delaware Consumer Fraud Act, 6 Del. C. §§ 2511, *et seq.*,

13. In Count V, Plaintiffs and the Class seek damages for unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state consumer protection statutes.

JURISDICTION AND VENUE

14. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. §§ 22 and 26. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. §1367(a).

15. Venue is proper within this District under 15 U.S.C. §22 and 28 U.S.C. §1391(b) because Defendants are found or transact business within this District, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this District.

16. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(d)(2), which provides federal district courts with original jurisdiction over civil actions in which the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interests and costs, and is a class action in which "any member of a class of plaintiffs is a citizen of a state different from any defendant."

TRADE AND COMMERCE

17. At all relevant times, TriCor® was manufactured by Defendants and was thereafter sold, shipped and transported across state lines to United States customers located outside the state of manufacture. In connection with the purchase and sale of TriCor®, monies, as well as contracts, bills, and other forms of business communications and transactions, were transmitted in a continuous and uninterrupted flow across state lines. Various means and devices were used to effectuate the Defendants' actions alleged herein, including the United States mail, interstate travel, interstate telephone commerce, and other forms of interstate electronic communications. The activities of Defendants alleged herein were within the flow of, and have substantially affected, interstate commerce.

THE PARTIES

Plaintiffs

Individual Consumers Plaintiffs

18. (a) Plaintiff Cindy Cronin is an individual and adult citizen of the State of California, residing in Valley Center, California.

(b) Plaintiff Diana Kim is an individual and adult citizen of the State of New York, residing in Brooklyn, New York.

(c) Plaintiff Sandra Krone is an individual and adult citizen of the Commonwealth of Pennsylvania, residing in Lafayette Hills, Pennsylvania.

(d) Alberto Litter is an individual and adult citizen of the State of Florida, residing in Miami-Dade County.

(e) Plaintiffs Neil and Helena Perlmutter are individuals and adult citizens of the State of Florida, residing in Port St. Lucie, Florida.

(f) Plaintiff Elaine M. Pullman is an individual and adult citizen of the State of Idaho, residing in Idaho Falls, Idaho.

(g) Plaintiff Lula Ramsey is an individual and adult citizen of the State of Virginia, residing in Madison Heights, Virginia.

(h) Plaintiff Charles M. Shain is an individual and adult citizen of the State of New York, residing in New York City.

(i) Plaintiff Hector Valdes is an individual and adult citizen of the State of Florida, residing in Miami, Florida.

(j) Plaintiff Richard G. Wilde is an individual and adult citizen of the State of

New Jersey, residing in Dunellen, New Jersey.

19. During the Class Period, each of the Individual Consumer Plaintiffs described above paid supra-competitive prices for some or all of the cost of fenofibrate products, other than for resale, and have thereby been injured as a result of Defendants' conduct.

Third-Party Payors Plaintiffs

20. (a) Plaintiff Allied Services Division Welfare Fund ("Allied Services"), a division of the Transportation Communications International Union AFL-CIO, CLC ("TCU"), is a health and welfare benefit fund with its principal place of business at Arlington Heights, Illinois. Allied Services is involved in the business of providing health and welfare benefits, among others, to covered lives. Allied Services is a multi-employer employee welfare benefit plan within the meaning of Employee Retirement Income Security Act (ERISA), 29 U.S.C. §§ 1002(2); 1002(37).

(b) Sheetmetal Workers International Association Local Union 28 ("Local28") is a duly organized labor union representing sheetmetal workers and is a member of the American Federation (AFL/CIO). The Union offices are located at 500 Greenwich St., New York, N.Y. 10013. The Sheetmetal Workers International Association Local Union #28, Funds and Plans is an "employee benefit plan" within the meaning of Employee Retirement Income Security Act (ERISA), 29 U.S.C. §§ 1002(1), 1002(3), 1003(a). The Funds and Plans office is located at 195 Mineola Blvd., Mineola, N.Y. 1150. Local 28 has approximately 2600 active members and approximately 1100 retirees. The Funds and Plans provide health and pension benefits to more than 5000 beneficiaries who reside primarily in the states of New York and New Jersey. One of the covered benefits is an annual prescription benefit of \$10,000.00.

(c) Plaintiff Painters' District Council No.30 Health and Welfare Fund ("the Painters' Fund") is located at St. Charles, Illinois and is an "employee welfare benefit plan" and an "employee benefit plan" within the Employee Retirement Income Security Act (ERISA), 29 U.S.C. §§ 1002(1), 1002(3), 1003(a). As such, the Painters' Fund is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). The Painters' Fund is a not-for-profit trust, sponsored by and administered by a Board of Trustees, established and maintained to provide comprehensive health care benefits to participant-workers, who are employed under various collective bargaining agreements, and to their dependents.

(d) Plaintiff Pennsylvania Employees Benefit Trust Fund (the "Pennsylvania Fund") is a labor-management trust fund duly organized under the laws of the Commonwealth of Pennsylvania, with its principal place of business in Harrisburg, Pennsylvania. The Pennsylvania Fund provides comprehensive healthcare benefits, including prescription drug coverage, to over 270,000 participants and beneficiaries, which includes active and retired employees of the Commonwealth of Pennsylvania and their spouses and dependents. Participants and beneficiaries of the Pennsylvania Fund reside in Pennsylvania, Delaware and a number of other states.

(e) Plaintiff Philadelphia Federation of Teachers Health and Welfare Fund ("Teachers' Fund") is located at 1816 Chestnut Street, Philadelphia, Pennsylvania and is a voluntary employee benefits plan organized pursuant to Section 501(d) of the Internal Revenue Code for the purpose of providing health benefits to eligible participants and beneficiaries. The Teachers' Fund provides health benefits, including prescription drug coverage benefits, to approximately 20,000 active participants and their spouses and dependents. Participants and

beneficiaries of the Teachers' Fund live in Pennsylvania and a number of other states.

(f) Plaintiff Vista Healthplan, Inc. ("Vista") is a private insurance company and health maintenance organization that provides health benefits to residents of Florida. Through agreements with participating pharmacies, Vista pays some or all of the cost of prescription drugs dispensed to its members. Vista is a Florida corporation and maintains its principal place of business in Hollywood, Florida.

21. During the Class Period, each of the Third-Party Payor Plaintiffs described above paid, at supra-competitive prices, for some or all of the cost of fenofibrate products, prescribed to one or more of their participants or beneficiaries and have thereby been injured as a result of Defendants' conduct.

Defendants

22. Defendant, Abbott, is a corporation organized, existing, and doing business under the laws of the state of Illinois. Its office and principal place of business is located at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott is engaged principally in the development, manufacture, and sale of pharmaceuticals and health care products and services. Abbott had sales of \$19.7 billion in 2004. Abbott operates in 130 countries and has facilities in 14 states.

23. Defendants, Fournier Industrie et Sante, formerly known as Fournier Innovation et Synergic, and Laboratoires Fournier, S.A., are French corporations having their principal place of business at 42 Rue de Longvie, 21300 Chenove, France. Abbott is the licensee from Fournier of the five patents listed in the Orange Book for TriCor® products.

RELEVANT MARKET

24. The relevant product market in which to assess the anticompetitive effect of

Abbott's and Fournier's conduct is the market for fenofibrate products, which consists of TriCor® products and generic bioequivalent versions of TriCor® products. Upon final approval from the FDA, generic fenofibrate products will be reasonably interchangeable, and will have a strong cross-elasticity of demand, with TriCor® products. At all relevant times, Defendants' market share in the relevant product and geographic markets was and between 95% and 100%.

25. The relevant geographic market is the United States as a whole (for Counts I and III, IV and V) and the Indirect Purchaser States (for Count II).

FACTUAL ALLEGATIONS

Brand Name Drugs—Generic Drugs

26. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, (the "FFDCA") approval by the FDA is required before a new drug can be manufactured and sold. Approval for a new drug, often referred to as a "pioneer drug," must be sought by filing a New Drug Application ("NDA") with the FDA demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are often covered by patents and marketed under a brand name.

27. Generic drugs are drugs which the FDA has found to have the same active chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs. Where a generic drug is bioequivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating. According to the FDA, a bioequivalent drug rated "AB" may be used and substituted interchangeably with the referenced branded drug.

28. Once the safety and effectiveness of a new drug is approved by the FDA, it may

be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be purchased from a licensed pharmacist. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician, unless an AB-rated generic version of that pioneer drug which has been approved by the FDA is available. Once a physician writes a prescription for a brand-name drug such as TriCor® capsules, that prescription can be filled only with the drug named or its AB-rated generic equivalents. Only generic drugs which carry the FDA's "AB" rating may be substituted by a pharmacist for a doctor's prescription for a brand-name drug.

29. If an AB-rated generic formulation of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most prescription drug benefit plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by prescription drug benefit plans, the pharmacist will offer the consumer the choice of purchasing the AB-rated generic at a lower price.

30. It is well recognized that, with the introduction of a generic pharmaceutical product, brand product sales immediately suffer a substantial loss, and the loss increases over time. A Congressional Budget Office ("CBO") Study in 1998, for example, showed that for twenty-one innovator drugs where generics entered the market from 1991-1993, in the first full calendar year of entry generics accounted for an average of forty-four percent (44%) of prescriptions dispensed through pharmacies. [C.B.O. Study at 28]. In the longer term, fourteen months after entry, the average generic market share was seventy-one percent (71%). [Henry

Grabowski and John Vernon, "Longer Patents for Increased Generic Competition: The Waxman-Hatch Act After One Decade", *PharacoEconomics*, 12 (1996)]. The erosion rates have increased significantly in recent times due to pressure from managed care to restrain increasing healthcare costs. In testimony before Congress, a representative from the Pharmaceutical Research and Manufacturers of America (a brand-name pharmaceutical manufacturers' trade association), confirmed that "in most cases, sales of pioneer medicines drop as much as 75 percent within weeks after a generic copy enters the market."

31. In addition to the loss in market share, the prices for generic products are significantly reduced over time and that reduction is directly related to the number of generic manufacturers entering the market. The reduction in price is significant when just one generic manufacturer enters the market. Typically the first generic company places the product on the market at 60% to 70% of the brand price. [Encyclopedia of Pharmaceutical Technology, *Generic Drugs and Generic Equivalency*, 458 (1992)]. Such prices still afford the generic manufacturer gross margins of 70% or better. [Id.]. When a second generic enters the market, prices of the generic product are likely to fall to between 50% to 60% of the brand price. [Id.]. Each subsequent competitor can lower the price further until five or more generics have entered the market, when the generic drug price can stabilize at 20% to 30% of the brand price. [Id.].

32. The 1998 CBO study also concludes that the average price of brand-name drugs facing generic competition is less than the average price of brand-name drugs without generic competition.

The Hatch Waxman Amendments

33. In 1984, Congress enacted the Hatch-Waxman Act to establish an abbreviated

process to expedite and facilitate the development and approval of generic drugs. 21 U.S.C. § 355.

34. The Hatch-Waxman Act permits a generic drug manufacturer to file an Abbreviated New Drug Application ("ANDA") that incorporates by reference the safety and effectiveness data developed and previously submitted in the NDA process by the company that manufactured the pioneer drug.

35. The FDA maintains and publishes *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), which lists all prescription drugs approved for use in the United States and the patents, if any, covering those drugs.

36. For each patent applicable to the pioneer drug listed in the Orange Book, an ANDA applicant must certify whether the proposed generic drug would infringe that patent and, if not, why not in accordance with FFDCA Section 355(j)(2)(A)(vii).

37. An ANDA filer must make one of four certifications in accordance with FFDCA Section 355(j)(2)(A)(vii):

- I. that no patent for the pioneer drug has been filed with the FDA;
- II. that the patent for the pioneer drug has expired;
- III. that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or
- IV. that the patent for the pioneer drug is invalid or will not be infringed upon by the generic company's proposed product (a "Paragraph IV Certification").

38. If an ANDA includes a Paragraph IV Certification, the applicant must notify the pioneer drug patent owner of the certification.

39. Upon receiving notification of a Paragraph IV Certification, the pioneer drug patent owner has 45 days under the Hatch-Waxman Act to initiate a patent infringement lawsuit against the ANDA applicant (the "45 day window"). If no lawsuit is initiated during the 45 day window, the process for FDA approval of the generic product continues.

40. If a patent infringement suit is commenced within the 45 day window, FDA final approval of the ANDA is automatically stayed until the earliest of: (a) the expiration of the patent; (b) the expiration of 30 months from the patent holder's receipt of notice of the Paragraph IV Certification (the "30 month stay"); or (c) a final judicial determination of non-infringement or patent invalidity.

41. The first filer of an ANDA with a Paragraph IV Certification is eligible for a 180-day period in which to market its generic version on an exclusive basis (the "180-day exclusivity period").

42. The 180-day exclusivity period is triggered by either: (a) commercial marketing of the generic product, or (b) a final court decision that the patent at issue is either invalid or not infringed.

43. Prior to the expiration of the 30 month stay, the FDA may grant "tentative" approval of an ANDA once it determines that all the criteria for "final" approval have been satisfied.

44. The Hatch-Waxman Act expressly permits the FDA to grant final approval to the first filed ANDA, and an ANDA applicant with FDA approval may market its generic product in the United States while the patent infringement lawsuit remains unresolved.

45. If a patent is listed in the Orange Book, the pioneer drug patent holder need only

file a patent infringement lawsuit within the 45 day window in order to block FDA approval of an ANDA applicant's generic drug from entering the market for up to 30 months.

46. If there are only Paragraph III certifications relative to a patent listed in the Orange Book, an ANDA is eligible for approval as soon as the patent expires, without delays associated with patent infringement litigation.

47. The Medicare Prescription Drug Improvement and Modernization Act of 2003, signed by President Bush on December 8, 2003, changed certain provisions of the Hatch-Waxman Act to curtail abuses by pharmaceutical manufacturers, such as precluding multiple 30-month stays.

Fenofibrate Products

48. Pharmaceutical products with the API fenofibrate reduce high levels of low-density lipoprotein cholesterol ("LDL-C"), sometimes referred to as "bad cholesterol," and triglycerides by promoting the dissolution and elimination of fat particles in the blood. Fenofibrate products also increase levels of high-density lipoprotein cholesterol ("HDL-C"), sometimes referred to as "good cholesterol," and reduce LDL-C in patients with primary hypercholesterolemia (high bad cholesterol) or mixed dyslipidemia (high bad cholesterol and high triglycerides). Fenofibrate products are also effective at reducing triglycerides in patients with hypertriglyceridemia (high triglycerides).

49. On February 9, 1998, Abbott received final approval for NDA No. 019304 for 67 mg fenofibrate capsules. On June 30, 1999, Abbott received final approval for 134 mg and 200 mg fenofibrate capsules. In connection with fenofibrate capsules, Abbott submitted to the FDA for listing in the Orange Book Patent No. 4,984,726 (the "'726 patent," which is also referred to

as the "Curtet Patent"), which was granted on January 23, 1990 to Fournier and exclusively licensed to Abbott in 1997.

Generic Manufacturers Apply To Market Fenofibrate Capsules

50. On December 14, 1999, Novopharm Ltd. filed an ANDA for 67 mg fenofibrate capsules (the "Capsule ANDA"). Novopharm sought approval to market its fenofibrate capsule product prior to the expiration of the '726 patent. Novopharm certified that its product did not infringe the '726 patent, and duly and timely notified Abbott of its ANDA. The ANDA was amended on March 31, 2000 and November 27, 2000 to include the 200 mg and 134 mg strength capsules.

51. Other generic manufacturers subsequently sought to market fenofibrate capsules, including Impax Laboratories, Inc. (ANDA filed May 9, 2000) and Reliant Pharms Inc. (NDA filed December 1, 2003).

52. On April 7, 2000, Abbott and Fournier sued Novopharm in the United States District Court for the Northern District of Illinois for infringement of the '726 patent based on Teva's Capsule ANDA for 67 mg and 200 mg fenofibrate capsules. Abbott's and Fournier's lawsuit triggered the automatic 30-month stay under the Hatch-Waxman Act, preventing the FDA from granting final approval to Teva's Capsule ANDA. In April 2000, Novopharm was acquired by Teva and thus became a Teva entity. On August 18, 2000, Abbott and Fournier also sued Impax for infringement of the '726 Patent, giving rise to a 30-month stay.

Abbott's and Fournier's First Market Switch: Capsules to Tablets

53. On December 10, 1999, in anticipation of applications to market generic fenofibrate capsules, Abbott filed NDA No. 021203 for 54 mg and 160 mg fenofibrate tablets,

which the FDA approved on September 4, 2001. When Abbott and Fournier thereafter launched sales of original TriCor® tablets, Abbott and Fournier touted the fact that the tablets had an additional indication for a high-density lipoprotein (HDL) effect, while TriCor® capsules had not been approved for HDL treatment. Both capsules and tablets, however, had the same HDL effect, so there was no medical difference between them in this regard. Abbott and Fournier actually used data obtained from capsules to obtain approval for the HDL indication for tablets. The same data used to obtain the HDL indication for tablets equally would have supported approval of the same HDL indication for capsules. The only reason TriCor® original formulation tablets had an approved HDL indication and TriCor® capsules did not is that Abbott and Fournier elected to apply for approval of that indication for tablets only. Abbott and Fournier did not want recognition that the capsules had this same HDL benefit; they wanted to tout their new tablets as having broader FDA-approved indications than the capsules in order to provide an apparent — but wrong — justification for the switch to tablets and the destruction of the capsule market.

54. Almost immediately upon receiving FDA approval for fenofibrate tablets in September 2001, Abbott and Fournier took affirmative steps to destroy the market for generic fenofibrate capsules and deprive patients of access to lower cost, generic fenofibrate products. Abbott and Fournier removed the fenofibrate capsule code from the NDDF, and they removed (or “obsoleted”) TriCor® brand fenofibrate capsules from the market. NDDF is a widely accepted database provided by First Databank, Inc. that includes drug descriptive and pricing information with an extensive array of clinical decision-support modules. This electronic drug information encompasses every drug approved by the FDA, including generic alternatives, and is used

throughout the healthcare industry. By removing TriCor® capsules from the NDDF, the branded drug code reference no longer exists for purposes of generic substitution laws or for purposes of health care providers' pharmaceutical benefit programs.

55. When they removed the capsules from the market, Abbott and Fournier also changed Abbott's sales force and stopped detailing the capsule formulation in the market. Abbott destroyed part of its existing inventory of TriCor® capsules rather than selling them. Abbott did so to speed up the pace of the market switch from capsules to tablets that Abbott and Fournier were imposing. By removing the capsule code from the NDDF, Abbott and Fournier rendered the TriCor® capsule code, to which generic capsules would have been compared, obsolete.

**Teva's Pyrrhic Victory on Fenofibrate Capsules – Approval
For a Product That Could No Longer Be Marketed as a Generic**

56. On March 19, 2002, the Illinois court granted Teva's motion for summary judgment of noninfringement of the '726 patent, clearing the way for Teva to market its generic fenofibrate capsule. On March 26, 2003, the Illinois court granted Impax's motion for summary judgment of non-infringement as well.

57. On April 9, 2002, as a result of the noninfringement decision, Teva received final FDA approval to market its 200 mg (as well as 134 mg) fenofibrate capsule products, and tentative FDA approval to market its 67 mg fenofibrate capsule products. Teva began to sell its 200 mg and 134 mg fenofibrate capsule products in April 2002. As the first filer of a Capsule ANDA with a Paragraph IV certification, Teva was granted a six-month exclusivity period during which the FDA was not permitted to grant final approval to another fenofibrate capsule ANDA. During an exclusivity period for a blockbuster drug such as TriCor® capsules, Teva

could reasonably expect to make well more than \$100 million in sales at prices substantially less than the price for branded TriCor® capsules.

58. Because of Abbott's and Fournier's anticompetitive tactics, however, the favorable decision and the exclusivity period proved to be a Pyrrhic victory for Teva. Because Abbott and Fournier removed TriCor® capsules from the NDDF, there was no longer a brand reference drug for Teva's fenofibrate capsules. Abbott's and Fournier's only purpose in removing the capsule code from the NDDF was to foreclose generic competition from Teva and other generic manufacturers in the fenofibrate product market. Had the capsule code not been removed from the NDDF (even if Abbott had ceased producing or marketing the products), there would still have been an NDDF reference for which Teva's generic capsules could have been substituted. Without the TriCor® capsule code as a reference, however, and without the continuation of Abbott's capsules in the marketplace, there was no longer a market for generic fenofibrate capsule products. Accordingly, most of the fenofibrate capsules that Teva had shipped to its customers were returned. Teva was effectively blocked from the market as a generic competitor in the fenofibrate market.

59. On October 7, 2002, the statutory 30-month stay on FDA approval of Teva's Capsule ANDA for 67 mg fenofibrate capsules ended, allowing Teva to enter the then-defunct capsule market with that dosage. On October 27, 2003, Impax was granted final approval to market its fenofibrate capsule products.

Teva Files ANDA to Market Fenofibrate Tablets

60. Blocked by Abbott's and Fournier's anticompetitive steps to preclude the marketing of generic fenofibrate capsules, Teva next sought to market generic fenofibrate tablets.

On June 17, 2002, Teva filed with the FDA an ANDA for its generic fenofibrate 54 mg and 160 mg tablets (the "Tablet ANDA"). In connection with its Tablet ANDA, Teva submitted a Paragraph IV certification that the ANDA did not infringe the '726 Patent, as well as two additional patents, U.S. Patent No. 6,074,670 (the "'670 Patent") and U.S. Patent No. 6,277,405 (the "405 Patent"). On August 21, 2002, Teva gave notice to Abbott and Fournier of the filing of the Tablet ANDA and the Paragraph IV certification made therein.

61. On October 4, 2002, in response to Teva's Tablet ANDA and August 21, 2002 letter, Abbott and Fournier filed patent infringement action Civil Action No. 02-1512, which asserts that Teva's Tablet ANDA infringes the '726 Patent, the '670 Patent, and the '405 Patent. Even though Teva provided Abbott and Fournier of samples of Teva's tablets for testing, they performed no tests to determine if Teva's tablets actually infringed the patents before bringing suit.

62. Abbott's and Fournier's patent infringement action against Teva concerning the '726 Patent, the '670 Patent, and the '405 Patent triggered an automatic 30-month stay under the Hatch-Waxman Act that prevented the FDA from granting final approval to Teva's Tablet ANDA for so long as the statutory stay remains in effect.

63. On July 8, 2003, the PTO granted Fournier U.S. Patent No. 6,589,552 (the "'552 Patent").

64. On July 23, 2003, Abbott and Fournier listed the '552 Patent in the Orange Book for TriCor® 54 mg and 160 mg tablets.

65. By July 29, 2003, Teva supplemented its Tablet ANDA by filing a Paragraph IV certification to the '552 Patent. By July 29, 2003, Teva gave notice to Abbott and Fournier of the

filing of its Paragraph IV certification to the '552 Patent.

66. On August 29, 2003, in response to Teva's Paragraph IV certification to the '552 Patent, Abbott and Fournier filed patent infringement action Civil Action No. 03-847. In their action, Abbott and Fournier claim that Teva's Tablet ANDA infringes the '552 Patent. Abbott's and Fournier's patent infringement action against Teva concerning the '552 triggered *another* 30-month automatic stay period under the Hatch-Waxman Act. This successive 30-month stay commenced and, absent a court decision, would continue in effect more than one year after the first 30-month stay that went into effect with the filing of the first action, C.A. No. 02-1512.

Abbott Submits NDA for New Tablet Formulations

67. On October 29, 2003, Abbott submitted NDA No. 021656 to the FDA for its new version of TriCor® fenofibrate tablets in 48 mg and 145 mg dosage forms. Abbott and Fournier did not seek FDA approval for this new formulation product until after they knew that Teva had developed generic fenofibrate tablets and was seeking approval to sell those tablets in the United States.

68. On November 25, 2003, the PTO granted Abbott U.S. Patent No. 6,0652,881 (the "'881 Patent").

69. On December 12, 2003, Abbott and Fournier listed the '881 Patent in the Orange Book for TriCor® 54 mg and 160 mg tablets.

70. On December 17, 2003, Teva supplemented its Tablet ANDA by filing a Paragraph IV certification to the '881 Patent. On December 17, 2003, Teva gave notice to Abbott and Fournier of the filing of its Paragraph IV certification to the '881 Patent.

71. On January 22, 2004, in response to Teva's Paragraph IV certification to the '881

Patent, Abbott and Fournier filed patent infringement action Civil Action No. 04-0047. In their action, Abbott and Fournier claim that Teva's Tablet ANDA infringes the '881 Patent. Because of the December 2003 amendments to the Hatch-Waxman Act to curtail such abuse, another 30-month stay was not available.

Teva Granted Tentative Approval For 54 mg and 160 mg Fenofibrate Tablets

72. On March 5, 2004, the FDA granted tentative approval to Teva's Tablet ANDA. By granting tentative approval, the FDA indicated that Teva's fenofibrate 54 mg and 160 mg tablets are bioequivalent to TriCor® tablets of the same dosage strengths. Due to the successive 30-month stays resulting automatically from Abbott's and Fournier's filing and maintenance of their patent infringement actions against Teva concerning Teva's Tablet ANDA, the FDA was legally precluded from granting final approval to Teva's Tablet ANDA until the stays expire or a court enters judgment in Teva's favor.

Abbott's and Fournier's Second Market Switch

73. On November 5, 2004, Abbott announced that it had received FDA approval to market the 48 mg and 145 mg TriCor® fenofibrate tablets. The new version tablets replace Abbott's 54 mg and 160 mg tablet dosage forms and are indicated for the exact same uses as the 54 mg and 160 mg tablet dosage forms.

74. Before FDA granted final approval for Teva's Tablet ANDA, Abbott and Fournier began marketing their new TriCor® tablet products, and they ceased supplying the market with the 54 mg and 160 mg TriCor® tablets. The supply of Abbott's and Fournier's 54 mg and 160 mg TriCor® tablets soon disappeared and Abbott and Fournier, once again, removed the brand reference code for these tablets from the NDDF.

75. On May 2, 2005, the first 30-month stay resulting automatically from Abbott's and Fournier's lawsuits concerning the '726 Patent, the '670 Patent, and the '405 Patent expired of its own terms. The FDA could not grant final approval to Teva's Tablet ANDA, however, due to the stay resulting from Abbott's and Fournier's subsequent action alleging infringement of the '552 Patent.

76. On May 6, 2005, the court ruled in the Tablet Lawsuits that Teva's product does not infringe the '552 Patent, the '670 Patent, or claim 9 of the '405 Patent. As a result of that decision, the subsequent automatic stay terminated. The very same day (and approximately one week before the FDA granted final approval to Teva's Tablet ANDA in light of that ruling) the code for Abbott's and Fournier's original formulation 54 mg and 160 mg TriCor® tablets was removed from (or reclassified as "obsolete" in) the NDDEF, at Abbott's and Fournier's direction. Abbott and Fournier acted to ensure, and did ensure, that the NDDEF codes were reclassified as obsolete before Teva could commence sales of its generic fenofibrate tablets. Thereafter, Teva's generic tablets would not be substitutable for any brand products.

77. On May 13, 2005, the FDA granted final approval to Teva's Tablet ANDA for fenofibrate tablets, 54 mg and 160 mg.

78. With final approval of Teva's Tablet ANDA, the purpose of Abbott's and Fournier's patent infringement litigation — *i.e.*, to delay generic entry to allow for another market switch — had run its course and served its anticompetitive purpose. Accordingly, on the same day that Teva announced final approval of its Tablet ANDA, May 16, 2005, Abbott and Fournier informed the judge presiding over the patent infringement actions that "they no longer wish to prosecute their consolidated patent infringement action against Teva and Impax."

79. On June 8, 2005, Abbott announced that it had "settled" its patent dispute with Teva.

"Patent litigation has been amicably resolved and the parties have agreed to dismiss the patent claims," said Jennifer Smoter, a spokeswoman for Abbott, reached by telephone. She said this will allow Teva to go ahead, if it wishes, with the launch of generic TriCor.

However, she stressed, Teva's generic drug would be the equivalent of Abbott's older formulation of TriCor, not the newer formulation that Abbott has been marketing since getting U.S. Food and Drug Administration approval last November.

[Dow Jones Newswire June 8, 2005].

80. On July 13, 2005, the Court approved the stipulation and order of dismissal of Abbott's and Fournier's patent claims.

Defendants Engaged in Inequitable Conduct before the PTO and Engaged in Sham Litigation to Unlawfully Maintain a Monopoly

81. Abbott's and Fournier's scheme unreasonably restrains competition even if their patent infringement actions against generic manufacturers are deemed lawful petitioning activity. As further alleged, however, Abbott and Fournier did not engage in protected petitioning activity.

82. Abbott is the licensee from Fournier of the five patents utilized to block generic competition for TriCor®: the '726 Patent (also referred to as the "Curtet Patent"), and the '670 Patent, the '405 Patent, the '552 Patent, and the '881 Patent (the latter four referred to collectively as the "Stamm Patents").

83. As detailed in Teva's Second Amended Answer, Affirmative Defenses, and Counterclaims ("Teva's Counterclaim"), filed July 29, 2005 [Doc. No. 369], Fournier committed inequitable conduct before the PTO in the prosecution of all four Stamm Patents. *See* Teva's

Counterclaim ¶¶ 105-182 (incorporated herein by reference). Fournier had highly material data in its possession showing that the Stamm Patents did not offer a better dissolution profile than that which existed through prior art, but it did not disclose such data to the PTO. Fournier repeatedly relied upon misleading dissolution profiles despite this data, which contradicted its essential arguments for patentability of the Stamm Patents. Philippe Reginault, the inventor of the Curtet patent who was employed by Fournier during the pendency of the application for all of the Stamm Patents,

[REDACTED]

84. In addition, Abbott and Fournier did not reasonably believe and could not have reasonably believed that they could properly assert a claim of patent infringement concerning the Stamm Patents due to the unenforceability of those patents. Abbott listed of the Stamm Patents in the Orange Book in order to position itself to invoke the statutory 30-month stay of FDA approval of generic formulations, in furtherance of Abbott's and Fournier's scheme to monopolize. Abbott and Fournier maintained and aggressively litigated the Tablet Lawsuits against Teva without hope of prevailing on the merits and solely to stall generic competition in order to complete their market switch. But for the wrongful listing of the Stamm Patents in the Orange Book and the subsequent actions that gave rise to statutory stays, the FDA would have approved generic versions of TriCor® much earlier. See Teva's Counterclaim ¶¶ 183-205 (incorporated herein by reference).

85. As alleged above, Abbott and Fournier filed and prosecuted patent infringement actions concerning Teva's ANDA for 54 mg and 160 mg generic fenofibrate tablets, triggering overlapping 30 month stays. These actions were in furtherance of Abbott's and Fournier's conspiracy to monopolize. Abbott and Fournier filed these actions even though they had no factual or legal basis — and knew that they had no factual or legal basis — for alleging infringement. Teva had provided samples of its generic fenofibrate tablets to Abbott and Fournier before Abbott and Fournier filed any of the patent infringement litigations, but Abbott and Fournier performed no tests of any kind on those tablets, including tests to analyze whether or not Teva's tablets might infringe Abbott's and Fournier's patents, before Abbott and Fournier filed all three of the lawsuits, alleging in each one that Teva's tablets infringed one or more of the patents. See Teva's Counterclaim ¶¶ 206-226 (incorporated herein by reference).

The Effects of Defendants' Anti-Competitive Conduct on the United States Market for Fenofibrate Products

86. The purpose of Defendants' anti-competitive conduct is to unlawfully maintain monopoly power in the market for fenofibrate products and their generic bioequivalents. But for the anticompetitive actions alleged herein, generic versions of TriCor® capsules would have been available to consumers from and after April 2002. When Teva launched its fenofibrate capsules in April 2002, however, no branded reference was available because Abbott had taken the unprecedented step of removing its brand reference code from the NDDF.

87. By removing TriCor® capsules from the NDDF, the branded drug code reference no longer exists for purposes of generic substitution laws or for purposes of health care providers' pharmaceutical benefit programs. For example, had Abbott not withdrawn TriCor® capsules from the NDDF, a pharmacist filling a prescription written for TriCor® capsules after

April 2002 would have been advised by a code reference in the database that a lower cost generic version of the drug was available. Thus, the pharmacist could, and often was legally required to, substitute the generic version for TriCor® capsules in filling the prescription. Similarly, prescription benefit plans provide tiered co-payment arrangement that are designed to steer consumers to lower cost generic drugs by requiring higher co-payments for branded drugs, e.g., a branded co-payment might be \$25, but only \$10 for the generic version of the same drug. These incentives result in a brand name drug quickly losing a significant portion of its market share soon after the introduction of generic competition, even if the brand name manufacturer lowers its price to meet competition. This is the very generic competition that Congress sought to facilitate when it adopted the Hatch-Waxman Act in 1984.

88. For fenofibrate products, however, Abbott and Fournier have perverted the system to undermine the purposes of the Hatch-Waxman Act and preclude consumer access to lower-cost generic fenofibrate products. By withdrawing TriCor® capsules from the NDDF and ensuring that a code reference for the branded drug no longer exists for purposes of the U.S. Healthcare system, a prescription for TriCor® capsules *cannot be filled by the pharmacist at all, not even with a bioequivalent substitute marketed by Teva*. Similarly, an insured consumer attempting to fill a prescription for TriCor® capsules will not be able to do so, and will not have the option of substituting a generic version for a lower co-payment.

89. Because the code reference for TriCor® capsules does not exist, Teva could not sell its fenofibrate capsules as a generic drug. In fact, most of the fenofibrate capsules that Teva shipped after the launch in 2002 were subsequently returned by customers because they could not be sold. Teva was forced to market its fenofibrate capsules as a branded product (under the trade

name Lofibra®) without the benefits of a generic classification for purposes of generic substitution laws or lower prescription benefit co-payments. Teva, like most generic manufacturers, does not employ an extensive marketing department like brand-name manufacturers and Lofibra® sales have been negligible (in the range of about \$4 million per year), barely scratching the surface of Abbott's and Fournier's fenofibrate monopoly. Other generic manufacturers have received FDA final approval to market fenofibrate capsules (Impax Labs on October 27, 2003 and Reliant Pharms on November 30, 2004), but they face the same barriers as Teva in penetrating Abbott's and Fournier's fenofibrate monopoly. By foreclosing the ability of generic manufacturers to market generic products, Abbott's and Fournier's anticompetitive acts imposed significant barriers to market entry on its would-be generic competitors and allowed Defendants to maintain supracompetitive prices for their fenofibrate products.

90. Defendants repeated this maneuver with the market shift to new tablet formulations. Abbott's and Fournier's conduct also will ensure that even if prescriptions for the 54 mg and 160 mg tablet formulations are written, no generic substitutions will be allowed. In order to accomplish this, Abbott and Fournier have ceased distribution of their 54 mg and 160 mg tablet formulations to the market and removed the reference code in the NDDF for their 54 mg and 160 mg tablet formulations. Without this reference code, it is illegal for a pharmacist to substitute a generic alternative of the 54 mg and 160 mg formulations for any prescription for the 54 mg and 160 mg tablet formulations.

91. But for Abbott's and Fournier's conduct, generic competition for fenofibrate tablets would have commenced more than six months before Abbott and Fournier could have

started converting the market to their new tablet formulation. Teva would have started selling its fenofibrate 54 mg and 160 mg tablets shortly after March 5, 2004, the date on which FDA granted tentative approval to Teva's Tablet ANDA. But for Abbott's and Fournier's conduct in wrongfully securing a 30-month stay, the FDA would have granted final approval to Teva's Tablet ANDA. Because Abbott and Fournier did not receive approval for their new formulation tablets until November of 2004, they could not have started their efforts to switch the market before that time. Had Teva been able launch generic fenofibrate tablets in March 2004, it would have captured significant sales through substitution for branded TriCor® tablets. Teva would have been able to maintain sales of 54 mg and 160 mg tablets even if Abbott and Fournier subsequently removed the reference for TriCor® 54 mg and 160 mg tablets from the NDDEF, as they did. If a generic fenofibrate formulation had been available on the market before Abbott and Fournier were able to complete the second market switch, many doctors and patients would begin to use (and then would continue to use) the generic fenofibrate tablets. There would also be pressure from the managed care industry for patients to continue to be prescribed the generic 54 mg and 160 mg tablets. Because Teva's generic tablets were not marketed before the switch were completed, however, Teva's product could not enter the market as the generic equivalent of a current brand-name drug and the managed care industry would not be in a position to exert pressure to switch patients who started using the new formulation back to the 54 mg and 160 mg tablets, once generic tablets become available.

92. Abbott's and Fournier's removal of the reference code in the NDDEF for its 54 mg and 160 mg tablet formulations will make it more expensive for any patients to use generic fenofibrate tablets in the event that any doctors continue to write prescriptions for 54 mg and/or

160 mg fenofibrate formulations. Patients will be forced to pay higher co-payment amounts for Teva's 54 mg or 160 mg fenofibrate tablets when there is no reference code for Abbott's and Fournier's TriCor® 54 mg or 160 mg tablets in the NDDF than they would be required to pay for the generic manufacturers' product if Abbott and Fournier had maintained the reference in the NDDF. This is because, without a reference code in the NDDF for TriCor® 54 mg or 160 mg tablets, generic manufacturers' tablets will be treated as a branded product rather than a generic product if listed in the NDDF, which would lead prescription benefit providers to require higher co-payments.

93. Abbott's and Fournier's replacement TriCor® tablets provide no significant medical benefit over the original formulation tablets for the majority of patients taking fenofibrate. Abbott and Fournier tout the replacement formulation tablets as a supposed "improvement" on the ground that, unlike the original tablets, the replacement tablets do not need to be taken with food. Abbott's and Fournier's own data, however, show that two-thirds of patients using TriCor® tablets take the medicine with food in any event. The bioavailability of the original tablets, when taken with food, is equivalent to the bioavailability of the new tablets, which means that those patients who took the original tablets with food derive no significant medical benefit from the replacement formulation that they did not already obtain from the original tablets. For the same reasons, Abbott's and Fournier's replacement TriCor® tablets provide no significant medical benefit for the majority of patients taking fenofibrate that those patients would not also obtain by taking generic fenofibrate tablets. In other words, the majority of patients on fenofibrate are just as well off with the prior formulation — whether brand or generic — but it is unavailable to them as a generic.

94. When one attempts to purchase a fenofibrate product, the current impact of Abbott's and Fournier's anticompetitive scheme is apparent. For example, online retailer drugstore.com sells nearly all branded and generic drugs, and encourages generic substitution with immediate price comparisons.

Generic vs. Brand Medications

Generic medicines are approved for use by the Food and Drug Administration (FDA) and are therapeutically equivalent to brand name products. In almost all cases, generics work just as well as their brand-name siblings and often cost considerably less.

Most states allow pharmacists to substitute a generic when appropriate and when you and your doctor authorize it. Our pharmacy is located in New Jersey, so we substitute generic drugs recognized as interchangeable under New Jersey law. If you and your doctor have authorized the use of generic medicines, our pharmacy will substitute your prescription with the generic equivalent.

An inquiry for a branded drug with an available generic version, such as Ativan®, is reported as follows:

Ativan (other types of Ativan)
generic: Lorazepam (learn more about brand vs. generic drugs)

Ativan - 1mg Tablets

Quantity	Our Price
○ 30 tablets	\$44.70
● 90 tablets	\$124.16
○ 100 tablets	\$137.95
○ 120 tablets	\$165.54
○ 150 tablets	\$209.82
○ 180 tablets	\$248.31

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Lorazepam - 1mg Tablets

Quantity	Our Price
○ 30 tablets	\$14.99
● 90 tablets	\$43.99
○ 100 tablets	\$48.99
○ 120 tablets	\$58.66
○ 150 tablets	\$73.32
○ 180 tablets	\$84.62

[View Details](#)

Source: drugstore.com [Sept. 19, 2005]

95. An inquiry for "trikor" [on September 19, 2005], however, produces results for only 48 mg and 145 mg Tricor® tablets, as follows:

Tricor (other types of Tricor)

Tricor - 48mg Tablets

Quantity	Our Price
<input type="radio"/> 30 tablets	\$35.32 - save 7% (\$2.70)
<input checked="" type="radio"/> 90 tablets	\$98.88 - save 13% (\$18.39)
<input type="radio"/> 100 tablets	\$109.84 - save 13% (\$17.10)
<input type="radio"/> 120 tablets	\$131.57 - save 13% (\$20.52)
<input type="radio"/> 150 tablets	\$164.46 - save 13% (\$26.86)
<input type="radio"/> 180 tablets	\$197.35 - save 13% (\$30.79)
<input type="radio"/> other: <input type="text"/>	<u>update price</u>
<input type="text"/>	Note: Savings calculated from <u>Average Retail Price</u>

Tricor (other types of Tricor)

Tricor - 145mg Tablets

Quantity	Our Price
<input type="radio"/> 30 tablets	\$83.50 - save 18% (\$20.58)
<input checked="" type="radio"/> 90 tablets	\$264.91 - save 23% (\$77.28)
<input type="radio"/> 100 tablets	\$294.34 - save 23% (\$85.87)
<input type="radio"/> 120 tablets	\$353.21 - save 23% (\$103.05)
<input type="radio"/> 150 tablets	\$441.51 - save 23% (\$128.81)
<input type="radio"/> 180 tablets	\$529.81 - save 23% (\$154.57)
<input type="radio"/> other: <input type="text"/>	<u>update price</u>
<input type="text"/>	Note: Savings calculated from <u>Average Retail Price</u>


Source: drugstore.com [Sept. 19, 2005]

There is no reference to TriCor® capsules or TriCor® tablets in 54 mg, 67 mg or 160 mg strength (none of which are currently manufactured), generic versions of those products, or Lofibra® capsules or tablets, none of which are bioequivalent to the TriCor® 48 mg or 145 mg tablets.

96. A inquiry for "fenofibrate" will also bring up a reference to Lofibra® capsules as a branded drug without a generic alternative, as follows:


Lofibra (other types of Lofibra)

Lofibra - 67mg Capsules

Quantity	Our Price
<input type="radio"/> 30 capsules	\$26.24
<input checked="" type="radio"/> 90 capsules	\$69.29 - save 14% (\$10.95)
<input type="radio"/> 100 capsules	\$76.99 - save 14% (\$12.17)
<input type="radio"/> 120 capsules	\$92.39 - save 14% (\$14.60)
<input type="radio"/> 150 capsules	\$115.48 - save 14% (\$18.26)
<input type="radio"/> 180 capsules	\$138.56 - save 14% (\$21.91)
<input type="radio"/> other: <input type="text"/>	<u>update price</u>
	Note: Savings calculated from <u>Average Retail Price</u>

Lofibra (other types of Lofibra)

Lofibra - 134mg Capsules

Quantity	Our Price
<input type="radio"/> 30 capsules	\$48.29 - save 6% (\$3.23)
<input checked="" type="radio"/> 90 capsules	\$133.34 - save 14% (\$21.23)
<input type="radio"/> 100 capsules	\$148.15 - save 14% (\$23.80)
<input type="radio"/> 120 capsules	\$177.78 - save 14% (\$28.31)
<input type="radio"/> 150 capsules	\$222.22 - save 14% (\$38.40)
<input type="radio"/> 180 capsules	\$266.67 - save 14% (\$42.47)
<input type="radio"/> other: <input type="text"/>	<u>update price</u>
	Note: Savings calculated from <u>Average Retail Price</u>

Lofibra (other types of Lofibra)**Lofibra - 200mg Capsules**

Quantity	Our Price
<input type="radio"/> 30 capsules	\$73.49 - save 8% (\$8.76)
<input checked="" type="radio"/> 90 capsules	\$205.79 - save 15% (\$34.95)
<input type="radio"/> 100 capsules	\$228.65 - save 15% (\$38.84)
<input type="radio"/> 120 capsules	\$274.38 - save 15% (\$46.61)
<input type="radio"/> 150 capsules	\$342.98 - save 15% (\$58.25)
<input type="radio"/> 180 capsules	\$411.57 - save 15% (\$69.91)
<input type="radio"/> other: <input type="text"/>	<u>update price</u>

Note: Savings calculated from Average Retail Price

Source: drugstore.com [Sept. 19, 2005]

97. As a result of Defendants' anti-competitive conduct, Plaintiffs and the Class have been financially injured. First, Plaintiffs and the Class have never had the opportunity to pay for lower-cost generic versions of fenofibrate products. Second, while Defendants have maintained their monopoly for fenofibrate products and generic equivalents, Plaintiffs and the Class have paid and reimbursed supra-competitive and artificially high prices for TriCor® products.

98. Defendants had and have no legitimate justification, economic or otherwise, for committing the violations of law alleged herein. Abbott's and Fournier's conduct in ending sales of certain strengths or formulations of their TriCor® tablets and their TriCor® capsules is purely private conduct. Removing a product reference from the NDDF does not involve any governmental petitioning activity.

CLASS ALLEGATIONS

99. Plaintiffs bring this class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, sub-sections 23(a) and 23(b)(2) and/or (b)(3), on behalf of a class defined as follows:

All persons or entities in the United States and its territories who purchased, paid and/or reimbursed for fenofibrate products, including TriCor® tablets and TriCor® capsules, intended for consumption by themselves, their families, or their members, employees or insureds (the "Class") during the period from April 9, 2002 through such time in the future as the effects of Defendants' illegal conduct, as alleged herein, have ceased (the "Class Period"). Excluded from the Class are all Defendants and their respective subsidiaries and affiliates, all governmental entities, and all persons or entities that purchased fenofibrate products: (i) for purposes of resale, or (ii) directly from any of the Defendants.

Count II applies to purchases of fenofibrate products in the Indirect Purchaser States.

100. The members of the Class are so numerous that joinder of all members is impracticable. Purchasers of fenofibrate products during the Class Period number in the millions nationally, and there are, at a minimum, thousands of fenofibrate purchasers in each state.

101. Defendants' unlawful, anti-competitive and inequitable methods, acts and trade practices have targeted and affected all members of the Class in a similar manner, *i.e.*, they have been overpaying for fenofibrate products due to the absence of competing generic versions of TriCor® tablets and TriCor® capsules in the marketplace, and will continue to pay supra-competitive prices so long as Defendants' scheme continues. Among the questions of law and fact common to the Class are:

- (a) whether, under common principles of antitrust and trade practice law, Defendants' methods, practices and acts, as alleged herein, including, but not limited to, withdrawing the reference code in the NDDF for TriCor® capsules, violate federal and state antitrust and/or consumer protection laws;
- (b) whether Defendants have monopolized and attempted to monopolize the market for fenofibrate products;
- (c) whether Defendants intentionally and unlawfully excluded competitors and potential competitors from the market for fenofibrate products and generic bio-equivalents of TriCor® formulations;
- (d) whether Plaintiffs and members of the Class are entitled to equitable and/or injunctive relief;

- (e) the amount of the overcharges or amounts paid or reimbursed by members of the Class for fenofibrate products over and above the amounts they would have paid or reimbursed in a competitive market unaffected by Defendants' illegal acts as alleged herein; and
- (f) whether under common principles of unjust enrichment, Defendants unjustly enriched themselves to the detriment of Plaintiffs and the Class, entitling Plaintiffs and the Class to disgorgement of all monies resulting therefrom.

102. Plaintiffs' claims are typical of those of the Class they represent because Plaintiffs and all of the Class members were injured and continue to be injured and/or threatened with injury in the same manner by Defendants' unlawful, anti-competitive and inequitable methods, acts and practices, *i.e.*, they have paid and continue to pay supra-competitive prices for fenofibrate products and will continue to be forced to do so until the Relevant Market is truly competitive and prices have stabilized to competitive levels.

103. Plaintiffs will fully and adequately protect the interests of all members of the Class. Plaintiffs have retained counsel who are experienced in antitrust and consumer class action litigation. Plaintiffs have no interests which are adverse to, or in conflict with, other members of the Class.

104. The questions of law and fact common to the members of the Class predominate over any questions which may affect only individual members.

105. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Plaintiffs know of no difficulty likely to be encountered in the management of this action that would preclude its maintenance as a class action.

106. In addition, Defendants have acted and refused to act, as alleged herein, on grounds generally applicable to the Class.

COUNT I

**(INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR
DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT)**

107. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

108. As alleged above, Defendants knowingly and willfully engaged in a course of conduct designed to unlawfully maintain and prolong their monopoly position in the market for fenofibrate products in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

109. Plaintiffs and the other members of the Class have been injured in their business or property by reason of Defendants' antitrust violation alleged in this Count. Their injury consists of being deprived of the ability to purchase less expensive, generic fenofibrate products, and paying higher prices for TriCor® products than they would have paid in the absence of the antitrust violation. The injury to Plaintiffs and the Class is the type of injury antitrust laws were designed to prevent, and the injury flows from Defendants' unlawful conduct. Plaintiffs and members of the Class are threatened with further injuries as a result of Defendants' continuing scheme, as alleged herein.

110. Plaintiffs and the Class seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anti-competitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

COUNT II

**(FOR COMPENSATORY AND MULTIPLE DAMAGES
UNDER THE ANTITRUST AND/OR CONSUMER PROTECTION
STATUTES OF THE INDIRECT PURCHASER STATES)**

111. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

112. Defendants' conduct described herein constitutes unlawful acts of monopolization, conspiracy to monopolize and attempts to monopolize, as well as prohibited deceptive acts and practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, as follows:

(a) Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev. Stat §§ 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;

(b) California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

(c) District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;

(d) Florida: The aforementioned practices by Defendants were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §§ 542.15, *et seq.*, and the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §§ 501.201, *et seq.*;

(e) Iowa: The aforementioned practices by Defendants were and are in

violation of the Iowa Competition Law, Iowa Code §§ 553.4, 553.5 (1997);

(f) Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*, and the Kansas Consumer Protection Act, Kan. Stat. Ann. §§ 50-623, *et seq.*;

(g) Louisiana: The aforementioned practices by Defendants were and are in violation of the Louisiana Monopolies Law, La. Rev. Stat. Ann. §§ 51:121, *et seq.*, and the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401, *et seq.*;

(h) Maine: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, and the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit. 5, §§ 205-A, *et seq.*;

(i) Massachusetts: The aforementioned practices by Defendants were and are in violation of the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93, and the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A;

(j) Michigan: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §§ 445.771, *et seq.*, and the Michigan Consumer Protection Act, §§ 445.901, *et seq.*;

(k) Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, *et seq.*, and the Minnesota Consumer Fraud Act, Minn. Stat. §§ 325F.67, *et seq.*;

(l) Mississippi: The aforementioned practices by Defendants were and are in violation of Miss. Code Ann. §§ 75-21-1, *et seq.*;

(m) Nebraska: The aforementioned practices by Defendants were and are in violation of Ne. Rev. Stat. §§ 59-801, *et seq.*;

(n) Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, *et seq.*, and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.*;

(o) New Jersey: The aforementioned practices by Defendants were and are in violation of the New Jersey Antitrust Act, N.J. Stat. Ann. §§ 56:9-1, *et seq.*, and the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1, *et seq.*;

(p) New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57-12-1, *et seq.*;

(q) New York: The aforementioned practices by Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, *et seq.*, and the New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.*;

(r) North Carolina: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, *et seq.*;

(s) North Dakota: The aforementioned practices by Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, *et seq.*, and the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, *et seq.*;

(t) South Dakota: The aforementioned practices of Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, *et seq.*, and deceptive

trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, *et seq.*;

(u) Tennessee: The aforementioned practices of Defendants were and are in violation the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, *et seq.*, and the Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq.*;

(v) Vermont: The aforementioned practices of Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*;

(w) West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, *et seq.*, and the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-6-101, *et seq.*; and

(x) Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§ 100.20, *et seq.*

113. As a result of the conduct described above, Plaintiffs and the Class have sustained and will continue to sustain substantial losses and damage to their businesses and property in the form of, *inter alia*, being deprived of the ability to purchase less expensive, generic versions of TriCor®, and paying prices for fenofibrate products that were higher than they would have been but for Defendants' improper and unlawful actions. The full amount of such damages are presently unknown and will be determined after discovery and upon proof at trial.

114. Plaintiffs and the Class seek damages, multiple damages, treble damages, and other damages as permitted by state law, for their injuries caused by these violations pursuant to these statutes.

COUNT III

**(FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE
TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS)**

115. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

116. As a result of their unlawful conduct described above, Defendants have been and will continue to be unjustly enriched. Defendants' unlawful acts include, for the reasons alleged above, improperly withdrawing the reference code in the NDDF for TriCor® capsules in order to impose barriers to entry for generic manufacturers seeking to compete in the Relevant Market. Defendants have been unjustly enriched, to the detriment of Plaintiffs and the Class by the receipt of, at a minimum, unlawfully inflated prices and illegal profits on their sale of TriCor® products. Defendants have benefitted from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of their ill-gotten gains resulting from the overpayments for TriCor® products made by Plaintiffs and the Class.

117. Plaintiffs and members of the Class are entitled to the amount of Defendants' ill-gotten gains resulting from Defendants' unlawful, unjust and inequitable conduct. Plaintiffs and the Class are entitled to the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiffs and the Class members may make claims on a *pro rata* basis.

COUNT IV

**(UNFAIR AND DECEPTIVE TRADE PRACTICES IN
VIOLATION OF THE DELAWARE CONSUMER FRAUD ACT)**

118. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

119. As described herein, Defendants have intentionally and repeatedly used deception, fraud, false pretense, false promise, misrepresentation, and/or concealment, suppression or omission of material facts in connection with their conduct before the PTO and in the sale or advertisement of TriCor, including but not limited to inequitable conduct before the PTO, the filing of fraudulently procured patents in the FDA's Orange Book, the prosecution of "sham" patent infringement litigation for purposes of foreclosing generic entry, preventing or suppressing competition from generic versions of the drug by removing the NDDC codes of earlier versions of the brand name drug so that there would not be any brand name version to which the generic versions approved by the FDA could be equivalent. Doctors, patients and third-party payors were misled by Defendants into believing that they must purchase TriCor® instead of generic versions of the discontinued forms of TriCor® at a fraction of the price. It was the intent of Defendants that others rely on said concealment, suppression or omissions.

120. Defendants knew that its misleading publications and representations as to TriCor® were being relied upon by physicians, Plaintiffs and the Class for the purpose of prescribing or paying claims for TriCor®.

121. Defendants have therefore violated the Delaware Consumer Fraud Act, 6 Del. C. §§ 2511, *et seq.*, in particular, 6 Del. C. § 2513(a), causing Plaintiffs and the Class to suffer damage in the form of payments for TriCor® that were substantially more than payments would have been for generic versions of TriCor® in its earlier forms.

122. Plaintiffs and the members of the Class are therefore entitled to an award of compensatory damages in an amount to be determined at trial.

COUNT V

**(UNFAIR AND DECEPTIVE TRADE PRACTICES IN
VIOLATION OF ALL STATES' CONSUMER PROTECTION ACTS)**

123. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

124. Alternatively, Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state consumer protection statutes listed below:

(a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

(b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. Code § 45.50.471, *et seq.*;

(c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

(d) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*;

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or have made false representations in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

(g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

(h) Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of 6 Del. Code § 2511, *et seq.*;

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, *et seq.*;

(j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

(k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. § 10-1-392, *et seq.*;

(l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

(m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

(n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1, *et seq.*;

(o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

(p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code § 714.1b, *et seq.*;

(q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

(r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

(s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

(t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

(u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

(v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

(w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

(x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

(y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

(z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.010, *et seq.*;

(aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

(bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

(cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

(dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

(ee) Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

(ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

(gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

(hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

(ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

(jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

(kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

(ll) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

(mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

(nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.*;

(oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

(pp) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

(qq) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

(rr) Defendants have engaged in unfair competition or unfair or deceptive or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

(ss) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-1 1-1, *et seq.*;

(tt) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, § 245 1, *et seq.*;

(uu) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

(vv) Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code. § 19.86.010, *et seq.*;

(ww) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

(xx) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*, and

(yy) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*

125. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and the Class have suffered actual economic damage by paying supra-competitive prices for branded TriCor® instead of the equally efficacious generic version.

WHEREFORE, Plaintiffs pray that:

- (a) the Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiffs' claims for declaratory, equitable and injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages; and declare Plaintiffs as representatives of the Class;
- (b) the conduct alleged herein be declared, adjudged and decreed to be in violation of Section 2 of the Sherman Act, of the statutes of the Indirect Purchaser States set forth above, and the common law of unjust enrichment;
- (c) Plaintiffs and each member of the Class be awarded damages and, where applicable, treble, multiple, and other damages, including interest;
- (d) Plaintiffs and each member of the Class recover the amounts by which Defendants have been unjustly enriched;
- (e) Defendants be enjoined from continuing the illegal activities alleged herein;
- (f) Plaintiffs and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law;
- (g) Plaintiffs and the Class be granted such other and further as the Court

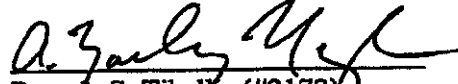
deems just and necessary.

JURY TRIAL DEMAND

Plaintiffs demand a trial by jury of all issues so triable in this case.

Dated: September 23, 2005

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